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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,014	03/26/2004	David G. Wild	CV0330 NP	9570
26079 7590 11/15/2007 BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			EXAMINER THANH, QUANG D	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,014

Applicant(s)

WILD ET AL.

Examiner

Quang D. Thanh

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2707 and 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 10/30/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/27/07 has been entered.
2. This office action is responsive to the amendment filed on 7/27/2007. As directed by the amendment, claim 1 has been amended, claims 4,6, 9, 12-13 and 15-18 have been cancelled. Thus, claims 1-3, 5,7, 8, 10,11, 14, 19 and 20 are presently pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5, 7-8, 10-11,14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barak in view of Calderon et al. (6,589,194).
4. Re claim 1, Barak discloses a compression device for the limb of a mobile patient (fig. 1) comprising: an inflatable sleeve 1 (fig.2) adapted to surround the limb; a

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conduit 4 attached to said sleeve for delivering fluid to said sleeve; and a portable, wearable controller 3 (fig. 1) or control unit 68 (col. 6, lines 63-67) attached to said conduit that generates and controls the flow of fluid in the device; wherein the sleeve includes a leg cuff and a foot cuff (fig. 2); the leg cuff comprises only three cells: a gaiter cell 2 adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2 adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2 adapted to wrap around the lower limb in the region between the mid-calf cell and the knee (best seen in fig. 2), except that it does not explicitly disclose that the sleeve includes consists of a leg cuff and a foot cuff. However, Barak teaches that "the invention is also intended for use on any body limb such as a foot, a part of a leg" (col. 4, lines 14-15) and "the number of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35). Moreover, Calderon et al. teaches a similar compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff consists of three cells: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to limit the Barak' device to include only a leg cuff and a foot cuff to treat the lower limb in the form a shoe, boot or stocking, as suggested by Calderon et al., for

the purpose of providing treatment of edema and varicose veins locally to a lower limb. Furthermore, since Barak already teaches that "various changes, **omissions** to the form and detail thereof may be made therein" (col. 10, lines 38-40), therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to eliminate the cell of the thigh, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

5. Re claims 2-3, 5, 7, Barak discloses the controller comprises a microprocessor control system (control unit 68, col. 6, lines 63-67) and a pump (pump unit 60, col. 6, lines 22-33); wherein at least one pressure sensor 62/63 or pressure monitoring means (col. 6, lines 37-38) is associated with said sleeve ; wherein said sleeve is low profile and discrete (fig. 1); said leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow (best seen in fig. 2).

6. Re claims 10-11 and 19, Barak discloses that the controller is battery operated (rechargeable battery pack 67, col. 6, lines 26-28); wherein each cell is monitored by a sensor 62/63 (col. 6, lines 37-38); and a method of preventing or treating edema or DVT (col. 2, lines 42-49) comprising applying a compression device of claim 1 to the limb of a mobile patient.

7. Re claims 8 and 20, Barak discloses the claimed inventions having all the features except for a sock interposed between the sleeve and the limb. Calderon et al. teaches a similar compression device having a sleeve comprising a plurality of cells 2A-D for treatment of edema and venous disorder (fig. 1). Further more, Calderon also teaches that the inner surface of the sleeve "is preferably smooth to engage the skin or a sock or stocking" (col. 3, lines 63-65), thus suggesting that a sock may be worn by the user and is interposed between the sleeve and the limb. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to further modify the Barak' device, to include a sock interposed between the sleeve and the limb, as suggested by Calderon et al., for the purpose of preventing skin irritation, skin shear and chaffing at the contact surface between the device and the skin of the limb during use.

8. Re claim 14, Barak discloses the claimed inventions having all the features except it is silent regarding the cells may be pressurized to the same or different predetermined pressures. However, Barak teaches (fig. 5) a pressure system 50 that has a range of pressure of 50-100 mmHg, and therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to operate the Barak's pressure system, such that the cells may be pressurized to the same or different predetermined pressures, for the purpose of providing a variety of compression therapy being applied on different body parts of the patient suitable to the patient's condition.

Response to Arguments

9. Applicant's arguments filed 7/27/2007 have been fully considered but they are not persuasive.

10. In response to applicant's argument that "Thus, from reading Barak, et al., one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device", the examiner respectfully disagrees. There is no evidence disclosed in Barak et al. to teach that the device would not work without the thigh cuff. Furthermore, since Barak already teaches that "the number of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35) and "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), therefore there appears to be no unobviousness for Barak to apply pressure only to the foot and leg, especially in view of the teaching of Calderon, which clearly teaches a compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff comprises only three cells: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1).

11. In response to applicant's arguments against the references individually that "Barak, et al. does not teach that treatment only below the knee is effective. The Barak, et al. device, for use on the leg, has a thigh cuff and a lower leg cuff. It is nowhere

suggested that the thigh cuff can be eliminated", one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the only difference between the present invention and Barak's device is that the thigh cuff is present. Calderon is cited to teach a compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff is consisted of three cells: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1). Therefore there appears to be no unobviousness for Barak to eliminate the thigh cuff to apply pressure only to the foot and leg, especially in view of the teaching of Calderon.

12. In response to applicant's argument that "Barak, et al. does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device", the applicant's attention is directed Barak's teaching in col. 10, lines 38-40, which clearly stated that "various changes, emissions to the form and detail thereof may be made therein" and thus omissions of the thigh cuff is possible, especially in view of the teaching of Calderon as discussed above. Applicant has not provided evidence that the Barak's device would not work effectively if the thigh cuff is eliminated. Moreover, it has been held that omission of an element and its function in a

combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (571) 272-4982. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The Central FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for all communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quang D. Thanh/

Quang D. Thanh,
Primary Examiner - Art Unit 3771
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